

**WE CLEAN HAND SANITIZER GEL - TEA TREE- alcohol liquid**  
**WeCool Toys, Inc.**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**Active Ingredient(s)**

Alcohol 62% v/v. Purpose: Antiseptic

**Purpose**

Antiseptic, Hand Sanitizer

**Use**

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

**Warnings**

For external use only. Flammable. Keep away from heat or flame

**Do not use**

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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**Directions**

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

**Other information**

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

**Inactive ingredients**

glycerin, hydrogen peroxide, purified water USP

**Package Label - Principal Display Panel**

NDC: 77006-003

1L/34.1 fl. hand sanitizer wrap label



**WE CLEAN HAND SANITIZER GEL - TEA TREE**

alcohol liquid

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC: 77006-003
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name		Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	58.36 g in 100 mL	
<b>Inactive Ingredients</b>				
Ingredient Name			Strength	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)				
ASCORBYL PALMITATE (UNII: QN83US2B0N)				
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)				
LINALOOL, (+/-)- (UNII: D81QY6I88E)				
HYDROLYZED JOJOBA ESTERS (POTASSIUM SALTS) (UNII: CH428W5O62)				
GLYCERIN (UNII: PDC6A3C0OX)				
WATER (UNII: 059QF0KO0R)				
DRY BIOCELLULOSE (MW 2000000) (UNII: C8DF2GF8L2)				
HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)				
ULTRAMARINE BLUE (UNII: I39WR998BI)				
LIMONENE, (+)- (UNII: GFD7C86Q1W)				
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)				
TROLAMINE (UNII: 9O3K93S3TK)				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77006-003-01	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:77006-003-02	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:77006-003-03	249 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
4	NDC:77006-003-04	1010 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	03/30/2020		

**Labeler** - WeCool Toys, Inc. (080480202)

**Registrant** - WeCool Toys, Inc. (080480202)

### Establishment

Name	Address	ID/FEI	Business Operations
Landy International		545291775	manufacture(77006-003) , label(77006-003) , pack(77006-003)

